UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,719	11/26/2003	Thomas Herget	AXM-009.3 US	4255

29425 7590 01/26/2006

LEON R. YANKWICH
YANKWICH & ASSOCIATES
201 BROADWAY
CAMBRIDGE, MA 02139

EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,719	HERGET ET AL.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Offfice Action is responsive to the communication received November 26. 2003. Claims 1-35 are pending.[1]

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method for detecting compounds useful for the prophylaxis and/or treatment of hepatitis C virus (HCV), classified in class 435, subclass 5.

II. Claims 2 and 3, drawn to a method for detecting HCV infection in an individual, cells, cell cultures or cell lystates, classified in class 435, subclass 5.

III. Claims 4-7 and 10-14, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering an agent which *activates the activity* of gastroinstestinal glutathione peroxidase, classified in class 435, subclass 192.

IV. Claims 4-14, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering an agent which *stimulates the production* of gastroinstestinal glutathione peroxidase by increasing DNA transcription, classified in class 536, subclass 24.5.

V. Claims 4-14, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering an agent which *stimulates the production* of gastroinstestinal glutathione peroxidase by increasing RNA translation, classified in class 536, subclass 24.5.

[1] The claim numbering omits claim 20. Thus, originally numbered claims 21 through 36 have been renumbered as claims 20 through 35 for the purposes of restriction. Applicants are requested to provide a renumbered copy of the claims with their response to this Office action.

VI. Claims 15-20, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering an antibody which *inhibits the activity* of gastroinstestinal glutathione peroxidase, classified in class 435, subclass 192.

VII. Claims 15-20 drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering an oligonucleotide which *inhibits the activity* of gastroinstestinal glutathione peroxidase, classified in class 435, subclass 192.

VIII. Claims 15-24, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering *an antibody* which *inhibits the production* of gastroinstestinal glutathione peroxidase by inhibiting DNA transcription, classified in class 424, subclass 172.1.

IX. Claims 15-24, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering *an antibody* which *inhibits the production* of gastroinstestinal glutathione peroxidase by inhibiting RNA translation, classified in class 424, subclass 172.1.

X. Claims 15-24, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering *an antibody* which *inhibits the production* of gastroinstestinal glutathione peroxidase by inhibiting DNA transcription and RNA translation, classified in class 424, subclass 172.1.

XI. Claims 15-24, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering *an oligonucleotide* which *inhibits the production* of gastroinstestinal glutathione peroxidase by inhibiting DNA transcription, classified in class 536, subclass 24.5.

XII. Claims 15-24, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering *an oligonucleotide* which *inhibits the production* of gastroinstestinal glutathione peroxidase by inhibiting RNA translation, classified in class 536, subclass 24.5.

XIII. Claims 15-24, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering *an oligonucleotide* which *inhibits the production* of gastroinstestinal glutathione peroxidase by inhibiting DNA transcription and RNA translation, classified in class 536, subclass 24.5.

XIV. Claims 25-27, drawn to a method for the selective killing of HCV infected cells in an individual comprising the step of administering a radical initiator, classified in class 435, subclass 235.1.

XV. Claims 28-33, drawn to a method for preventing and/or treating HCV infection in an individual or in cells comprising administering an antioxidant which is capable of supporting the function of gastroinstestinal glutathione peroxidase, classified in class 435, subclass 235.1.

XVI. Claims 34 and 36, drawn to a composition comprising an agent capable of inhibiting the activity of gastroinstestinal glutathione peroxidase, classified in class 435, subclass 192.

XVII. Claims 34 and 36, drawn to a composition comprising an agent capable of decreasing the expression of gastroinstestinal glutathione peroxidase, classified in class 536, subclass 24.5.

XVIII. Claims 35 and 36, drawn to a composition comprising an agent capable of increasing the activity of gastroinstestinal glutathione peroxidase, classified in class 435, subclass 192.

XIX. Claims 35 and 36, drawn to a composition comprising an agent capable of stimulating the expression of gastroinstestinal glutathione peroxidase, classified in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I is unrelated to Inventions III-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Here, the specification does not describe a process that uses the steps of Invention I with the steps of Inventions III-XV. That is, there is no disclosure of a method that uses detecting human cellular protein gastrointestinal glutathione peroxidase activity in connection with modulating the production or activity of glutathione peroxidase. Invention I also has a different function than Inventions III-XI. This results as the objective of Invention I is to detect anti-HCV compounds, while Inventions III-XI are methods for treating and/or preventing infection. Inventions I is therefore unrelated to Inventions III-XI.

Invention II is unrelated to Inventions III-XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Here, the specification does not disclose a process that uses the steps of Inventions II with the steps of Inventions III-XV. That is, there is no disclosure of detecting gastroinstestinal glutathione peroxidase in combination with administering an agent that activates or increases it. Invention II also has a different function than Inventions III-XV since Invention II detects HCV infection while the objective of Inventions III-XV is to treat HCV infection. Invention II is therefore unrelated to Inventions III-XV.

Inventions I and II are unrelated. The specification does not disclose a process that incorporates the steps of Inventions I and II. Ivnentions I and II are therefore not disclosed as useable together. Inventions I and II also have different functions. Invention I is drawn to identifying anti-HCV therapeutics, while Invention II serves as an HCV diagnostic. Therefore, Inventions I and II are unrelated.

Inventions III, VI and VII are unrelated to Inventions IV, V and VII-XIII. The specification does not disclose a process that involves simultaneously modulating the activity of gastroinstestinal glutathione peroxidase (Inventions III, VI and VII) and regulating the activity of this enzyme (Inventions IV, V and VII-XIII). The specification does not therefore disclose that Inventions III, VI and VII are useable with Inventions IV, V and VII-XIII. These different process steps also give the inventions different modes of operation. Accordingly, Inventions III, VI and VII are unrelated to Inventions IV, V and VII-XIII.

Inventions III-V are unrelated to Inventions VI-XIII due to their different modes of operation. Inventions III-V are drawn to processes that upregulate gastroinstestinal glutathione peroxidase. Inventions VI-XIII in contrast downregulate this enzyme.

Inventions IV and V are unrelated due to different modes of operation. Invention IV stimulates the production of gastroinstestinal glutathione peroxidase by increasing DNA transcription. Invention V in contrast stimulates RNA translation.

Inventions VI and VII are unrelated due to different modes of operation. Invention VI inhibits the activity of gastroinstestinal glutathione peroxidase by administering an antibody. Invention VII in contrast inhibits this enzyme through the administration of an oligonucleotide. Oligonucleotides have a different chemical composition and biological functions than antibodies. Therefore, these agents accomplish their therapeutic effect through different modes of operation.

Inventions VIII and IX are unrelated due to different effects. This results as Invention VIII inhibits DNA transcription, while Invention IX modulates RNA translation.

Inventions VIII and IX are related to Invention X as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination (Invention IX) does not derive patentability from either the inhibition of DNA transcription (Invention VIII) or the inhibition of RNA translation (Invention IX) alone. That is, the patentability of the subcombination may be established through the unobvious combination of Inventions VIII and IX.

Inventions VIII-X are unrelated to Inventions XI-XIII due to different modes of operation. Inventions VIII-X inhibit gastrointestinal glutathione peroxidase production by administering an antibody. Inventions XI-XIII in contrast administer an oligonucleotide. As noted above, antibodies and oligonucleotides have distinct chemical compositions and biological properties. Inventions VIII-X are therefore unrelated to Inventions XI-XIII.

Invention XI is unrelated to Invention XII due to different effects. Invention XI inhibits DNA transcription, while Invention XII modulates RNA translation.

Inventions XI and XII are related to Invention XIII as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination (Invention XIII) does not derive patentability from either the inhibition of DNA transcription (Invention XI) or the inhibition of RNA translation (Invention XII) alone. That is, the patentability of the subcombination may be established through the non-obvious combination of Inventions VIII and IX.

Inventions I and II are unrelated to Invention XIV because of their different functions. Invention I and II are respectively drawn to identifying anti-HCV compounds and diagnosing HCV. Invention XIV in contrast is a method for selectively killing HCV-infected cells.

Invention XIV is unrelated to Inventions III-XIII, XV-XIX due to different modes of operation. Inventions XIV functions by selectively killing HCV-infected cells. However, Inventions III-XIII function by modulating the activity or production of gastrointestinal glutathione peroxidase.

Inventions XVI and XVII are unrelated due to different modes of operation. Invention XVI is drawn to a composition for inhibiting the activity of gastrointestinal glutathione peroxidase, while Invention XVII decreases the production of this enzyme.

Inventions XVIII and XIX are unrelated due to different modes of operation. Invention XVI is drawn to a composition for increasing the activity of gastrointestinal glutathione peroxidase, while Invention XVII stimulates the production of this enzyme.

Inventions XVI and XVII are unrelated to Inventions XVIIII and XIX due to different modes of operation. Inventions XVI and XVII downregulate gastrointestinal glutathione peroxidase, while Inventions XVIIII and XIX upregulate this enzyme.

Inventions XVI-XIX are related to Inventions III-XV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products (i.e. antibodies and oligonucleotides) of Inventions XVI-XIX may be used to detect the presence of gastrointestinal glutathione peroxidase, or polynucleic acids that encode this enzyme.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

An election of any one of Inventions III-V requires a further election of a combination of agents from claims 11-14. These agent combinations are distinct from one another due to their distinct chemical compositions and biological activities.

An election of Invention XIV requires a further election of a radical initiator from claim 27. These initiators are distinct from one another due to their distinct chemical compositions and biological activities.

An election of any Invention XV requires a further election of an antioxidant from claim 30. These antioxidants are distinct from one another due to their distinct chemical compositions and biological activities.

An election of any Invention XV requires a further election of an agent selected from claim 30. These agents are distinct from one another due to their distinct chemical compositions and biological activities.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted

after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

JAMES HOUSEL 1/23/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600